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PATENT & TRADEMARK OFFICE

S/N 10/684,129 **PATENT**

Applicant: Stacey L. Schultz-Cherry et al.
Serial No.: 10/684,129
Filed: October 10, 2003
Title: METHOD TO DETECT ANTIBODIES SPECIFIC FOR TYPE-2 TURKEY ASTROVIRUS

Examiner: Benjamin P Blumel
Group Art Unit: 1648
Docket No.: 800.039US1

DECLARATION UNDER 37 C.F.R. § 1.132

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Dr. Stacey Schultz-Cherry, declare and say as follows:

1. I am one of the named co-inventors of subject matter claimed in the above-identified application, Serial No. 10/684,129, filed on October 10, 2003, and make this Declaration in support of the patentability of the claims in the above-identified application.

2. In the Office Action dated May 31, 2006, the Examiner rejected claims 1-7, 9-20, 22-23, 27-32, and 34 under 35 U.S.C. § 103(a) as being unpatentable over Monroe et al. (U.S. Patent No. 5,625,049) and Koci et al. (J. Virology, 74:6173 (2000)) and further in view of Mueller-Lantzsch et al. (U.S. Patent No. 5,858,723). Claim 21 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Monroe et al., Koci et al. and Mueller-Lantzsch et al., and further in view of Kim et al. (WO 92/20803).

3. The Examiner is apparently of the opinion that a general disclosure of an assay to detect antibodies to a particular virus, and a RT-PCR based assay for a particular virus, render obvious an assay to detect seroconversion for type-2 turkey astrovirus.

4. However, there are a number of obstacles to overcome when designing a serological assay. First, you need to identify the viral protein recognized by the immune response. Second, you must express the recombinant protein of interest in the proper conformation for identification by antibodies. This is often problematic. Third, one must then determine the conditions to express the protein for identification by antibodies in a physiological sample. This is commonly done using known positive antisera. Fourth, the actual assay can be

tricky to design, especially with avian serum, which is loaded with cholesterols. In addition, for an assay to be useful, the reagents and conditions must result in sufficient specific binding and low non-specific binding.

5. None of Monroe et al., Koci et al., Mueller-Lantzsch et al., or Kim et al. provide data evidencing a successful assay to detect seroconversion associated with viral infection, e.g., astrovirus infection.

6. Moreover, although there is a commercially available human astrovirus assay, and an antigen capture assay has been described for turkey astrovirus (see enclosures), both assays detect virus infection not seroconversion. Further, both of those assays employ fecal or intestinal content samples. In contrast, the claimed method employs a blood sample to detect seroconversion.

7. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 11-29-06

By: Stacey Schultz Cherry
Dr. Stacey Schultz-Cherry

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☐ **1:** Avian Dis. 2005 Jun;49(2):182-8. Links

Development of antigen-capture enzyme-linked immunosorbent assay and RT-PCR for detection of turkey astroviruses.

Tang Y, **Ismail MM**, **Saif YM**.

College of Veterinary Medicine, Jiangxi Agricultural University, Nanchang, 330045, PR China.

Turkey astrovirus (TAstV) is an important agent of poult enteritis. The diagnosis of astroviruses has been dependent mainly on electron microscopy (EM) or immune EM (IEM). To develop other simple, rapid, and reliable diagnostic assays, two antigen-capture enzyme-linked immunosorbent assays (AC-ELISAs), polyclonal AC-ELISA and monoclonal AC-ELISA, were developed in this study. Monoplex and multiplex reverse transcription-polymerase chain reactions (RT-PCRs) were also developed using nondegenerate primer sets specific to the capsid region and degenerate primer pairs specific to the polymerase area of two TAstV. EM was included for comparison. Fecal or intestinal contents samples from naturally and experimentally infected poults with enteritis were examined using the developed assays. The polyclonal AC-ELISA had higher sensitivity and wider detection spectrum than the monoclonal AC-ELISA with group-specific monoclonal antibody (MAb), whereas the monoclonal AC-ELISA had very high specificity but lower sensitivity, which was estimated at 0.06 microg of viral proteins. Small round viruses (SRV) that could be astroviruses or other small viruses were detected in 34.4% of the samples examined by EM. The monoplex RT-PCR results amplified with primers SRV-1-3 and SRV-1-5 revealed that the positive rate of astroviruses was 45.3%, which was 10.9% higher than that of EM even if other SRVs were not excluded. Multiplex RT-PCR with SRV-1-3 and SRV-1-5 and AFCP-F1 and AFCP-R1 and the monoplex RT-PCR with degenerate primers verified that the positive rate of astroviruses was 59.4%, which was 25% higher than that of EM. Both RT-PCRs showed good specificity and wider detection spectrum compared with earlier published data.

PMID: 16094820 [PubMed - indexed for MEDLINE]

Related Links

Development of a ssRNA internal control template reagent for a multiplex RT-PCR to detect turkey astroviruses. [J Virol Methods. 2005]

Development of a multiplex reverse transcription-polymerase chain reaction diagnostic test specific for turkey astrovirus and coronavir [Avian Dis. 2004]

Development of an RT-PCR diagnostic test for an avian astrovirus. [J Virol Methods. 2000]

Characterization of a small round virus associated with the poult enteritis and mortality syndrome [Avian Dis. 2000]

Molecular characterization and typing of chicken and turkey astroviruses circulating in the United States: implications for diagnosis [Avian Dis. 2005]

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